

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

# IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO  
01-CV-12257-PBS AND 01-CV-339

Judge Patti B. Saris

Chief Magistrate Judge Marianne B. Bowler

**PLAINTIFFS' OPPOSITION TO AMGEN INC.'S MOTION TO DISMISS PLAINTIFFS'**  
**CORRECTED AMENDED MASTER CONSOLIDATED COMPLAINT**

## I. INTRODUCTION

At the heart of Amgen’s motion to dismiss is the premise that the “CAMCC adds nothing in the way of additional detail regarding Amgen’s involvement in the so-called AWP scheme.” Amgen Mem. at 3.

However, Amgen’s argument simply ignores the amendment’s detailed and specific allegations concerning Amgen’s participation in the AWP scheme. The new allegations specify examples of Amgen’s misconduct, identify fraudulent AWP’s for Amgen’s drugs and identify the resulting spreads. Such specification satisfied plaintiffs’ burden with respect to other defendants and does so here as well. The allegations do not seek liability for “guilt by association,” but impose liability for “participation” in the AWP scheme based on specific examples of AWP manipulation all in the context of the general scheme the Court has already recognized. Given

the fact that Amgen has not been subject to discovery, these allegations satisfy Fed. R. Civ. P. 9(b).

## II. AMGEN'S MOTION SHOULD BE DENIED

### A. The Appropriate Legal Background

In *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 208 (D. Mass. 2004) (“*AWP II*”), the Court addressed Rule 9(b) as follows:

In *Pharm. I*, the Court held that in light of the detailed fraudulent scheme alleged, the plaintiffs’ allegations were sufficient with respect to “any drug identified in the complaint together with the allegedly fraudulent AWP published by a named defendant for that drug.” 263 F. Supp. 2d at 194. The Court instructed that if plaintiffs were to file an amended complaint, “plaintiffs shall clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug.” *Id.*

With respect to most Defendants, the Court finds that Plaintiffs in the AMCC have pled allegations concerning the fraudulent scheme with enough specificity to comply with the requirements of Rules 9(b) and 8(a). See *Franklin ex rel. v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (Saris, J.) (“[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the False claims Act have not placed the bar so high as to require pleading with total insight.”). In the AMCC, Plaintiffs describe extensively the factual investigations undertaken that formed the bases of Plaintiffs’ allegations, and in so doing identify particular allegedly-fraudulent conduct on the part of each Defendant, except one. (See ¶¶ 155-157 (describing government investigations); 187 (chart displaying spreads calculated by Department of Justice for eleven defendants); 200-540 (descriptions of varying specificity by particular defendant of pricing mechanisms, government investigations, internal documents identifying spread, and related items).) The amendments to the original complaint allege the particular drugs involved, and the AWP’s for those drugs. Compare *Pharm. I*, 263 F. Supp. 2d at 193-94.

The Court in *AWP II* went on to dismiss Hoffman-LaRoche on the grounds “this is essentially a guilt by association claim as there are no allegations concerning government investigations, *internal documents or specific fraudulent spreads relating to this company.*”

Amgen then moved to reconsider on the grounds that it too was in the same position as Hoffman-LaRoche, *i.e.*, that the allegations were guilt by association. Its motion was granted with plaintiffs being provided with leave to amend.

**B. The Amended Allegations Provide Detail of Specific Fraudulent Spreads, Internal Documents and Marketing Practices**

Unlike other defendants, Amgen did not produce any discovery prior to the filing of the AMCC, nor has it been the subject of governmental investigation. However, the Amended Amgen Allegations (“AAAs”) supplement the industry practice allegations that the Court recognized with specific examples of AWP manipulation by Amgen, from which more than a reasonable inference can be drawn as to Amgen’s participation in the AWP scheme.

First, the AAAs identify the motivation for Amgen’s marketing the spread. In attacking the AMCC, certain defendants claimed that where a drug had no competitors it would not need to market the spread and thus had no motive to participate in AWP manipulation. Plaintiffs disagree with this argument but as to Amgen the AAAs begin by identifying the competitive landscape. Amgen’s Aranesp has been locked in a fierce battle with Ortho’s Procrit, thus providing each company with an incentive to compete based on spread. ¶¶ 218-19. Similarly, Amgen’s Neupogen was locked into a competitive battle with Immunex’s Leukine, and this competition spawned a breeding ground for selling and marketing the spread. ¶ 219.

The AAAs then allege that Amgen sales representatives for both Aranesp and Neupogen handed out calculations showing the spread off of AWP that could be made or orally described that spread to physicians. ¶ 221A.

The AAAs then demonstrate the “specific fraudulent spreads,” as required by *AWP I* and *AWP II*. For example, on its website, Amgen posts its current AWP on Aranesp. ¶ 222. And it calculates the impact of such AWP on payors or patients. *Id.*

The AAAs then identify the specific AWP abuse that Amgen is engaging in right now on Aranesp, including discounts of 50% of the AWP posted on the website. Thus, the AWP posted on the website, which does not include such discounts, is a phony number. Thus, for a co-payor using Aranesp, as a result of Amgen’s posting a phony AWP, that patient has an increased co-pay of \$360 to \$480 as a result of the scheme. This is a specific set of allegations documenting Amgen’s abuse of the AWP reimbursement scheme and its impact on elderly Class members. The AAAs then detail how this type of discounting occurred prior to 2004, and actually started when Aranesp was introduced. ¶ 224B.

The AAAs also detail the competition between Leukine and Neupogen and how Immunex was promoting its spread. ¶ 225A. In response to Immunex’s promotion of its spread for Leukine, Amgen created a spread of 31% for Neupogen, which given the high price of Neupogen, substantially impacted co-payors and third-party payors. *Id.* This competition based on the spread was noticed by competitors and provides confirmation of Amgen’s participation. ¶ 225B. The AAAs then, consistent with the Court’s requirement that spreads be identified, does so for each year of the Class period for Neupogen. ¶ 226A. And, for Epogen, the AAAs establish a spread of 92% and 105% for certain dosages.

The AAAs plainly satisfy the Court's pleading requirements for this case as they allege specific spreads and cite from internal documents such that the allegations are not akin to "guilt by association" but plainly allege "*guilt by participation*."

### III. EACH OF AMGEN'S ARGUMENTS FAILS

#### A. The Fact That AWP Fraud Continued After This Action Was Filed Is Not Relevant

In order to deflate the obvious AWP manipulation with respect to Aranesp, Amgen now posits the new argument that any misconduct occurring after the filing of the first AWP complaint cannot be actionable as the fraud was not relevant because there could be no fraud once any AWP allegations were made. This argument is misplaced for two reasons. First, there are roughly 65,000 prescription drugs, and surely Amgen and the other defendants do not contend that the AWPs are inflated on all of these drugs or that plaintiffs should bring suit on each drug immediately because the filing of the AMCC put plaintiffs on notice that the AWP for every drug sold in America is phony. Rather, whether or not a given AWP is reliable or inflated by the scheme is discovered on a drug-by-drug basis. Since the original filing of the complaint plaintiffs have discovered that Amgen is posting phony AWPs on Aranesp and vigorously marketing the spread created as a result. Inclusion of Aranesp is certainly proper and the fraud is not mooted by the filing of the original case. In addition, the filing of the original cases does not put co-payors in Nebraska or New Mexico or any other state on notice. The fact is the AWP they are now making a co-payment on is false. The filing of the lawsuit does not vitiate that fraud or the resulting overpayment.

Second, as to relevancy, the fact that Amgen is so plainly and vigorously publishing phony AWPs on Aranesp helps with the inference, along with other allegations, that it would

engage in such practices with respect to other drugs as well, particularly when spreads on such drugs are identified in the AAAs.

**B. Phony AWP's Are Unlawful**

In *In re Pharmaceutical Indus. Average Wholesale Price Litig.* (“AWP I”), the Court held that in light of the detailed fraudulent scheme alleged, plaintiffs’ allegations were sufficient with respect to “any drug identified in the complaint together with the allegedly fraudulent AWP ....” 263 F. Supp. 2d 172, 194 (D. Mass. 2003). The AAAs have complied with the Court’s order as the specific drug, the AWP and the fraudulent spread have been identified.

In response, Amgen now argues that there is nothing unlawful about offering discounts and that the discounts are not “tied to an inflated AWP.” Amgen Mem. at 4. Nonsense. The AAAs, for example, identify the published AWP's and then provide specific examples of the spreads being offered. *See, e.g.*, ¶ 222 identify AWP's versus discounts in ¶¶ 223B, 224A, 224B. According to the complaint these discounts render the AWP's inflated and phony and under the Court’s prior rulings are thus actionable.

**IV. CONCLUSION**

Amgen’s motion simply ignores the now specific allegations which comply fully with this Court’s prior Orders as to the types of allegations necessary for a proper claim.

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**CERTIFICATE OF SERVICE**

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing **PLAINTIFFS' OPPOSITION TO AMGEN INC.'S MOTION TO DISMISS PLAINTIFFS' CORRECTED AMENDED MASTER CONSOLIDATED COMPLAINT** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on August 9, 2004, a copy to Verilaw Technologies for Posting and notification to all parties

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